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The Florida Lab Link

Packaging 6.2 Infectious Substances and other dangerous goods

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In an effort to reduce the risk of laboratory acquired infections or exposure to infectious substances, today's laboratorians are encouraged to think about safety issues not previously considered. A "culture of safety" encourages diagnostic laboratories to promote a systematic assessment of all work processes and procedures to identify associated risks and implement plans to mitigate those risks when handling diagnostic specimens, as well as the unknown biohazard risks associated with them.

Standardized operating procedures, protocols, engineering controls and personal protective equipment (PPE) are in place to protect bench technologists from biohazard risks as they analyze patient specimens. As the need to ship specimens to the state public health laboratory or other laboratory for further analysis arises, the assessment of risk to non-laboratorians, such as shipping personnel, must be considered.

The responsibility falls to the shipper to package the specimen using regulations that outline the minimum requirements needed to protect against leakage during transport and communicate potential risks to the carriers, consignees and the public through proper markings and

(Continued on page 2)

Inside this issue:

Special points of interest:

- *2016 Division 6.2 Infectious Substances Packaging and Shipping Training Schedule*
- *Chemical Threat Training*
- *Biological Defense Training*

PACKAGING 6.2 INFECTIOUS SUBSTANCES AND OTHER DANGEROUS GOODS (CONTINUED)

(Continued from page 1)

labels on the shipping containers. Whether using a commercial carrier like Fed Ex, United Parcel Service (UPS), the United States Postal service or if the package is hand carried to the laboratory by a private courier, it is a requirement that the shipper use the appropriate shipping container with all the correct labels and markings to prevent exposures. An exposure may occur if a package containing an infectious substance ruptures or leaks and the infectious substance is released outside the package.

Prior to packaging a specimen for transport, the shipper must correctly classify the contents including any preservatives or refrigerants used. Classification is the process that establishes whether a material is a dangerous good, and which Class or Division of dangerous goods it should be assigned. Consider dry ice. Many believe that "working with dry ice is not a big deal, kids play with it on Halloween. Don't put your tongue on it."

Photograph 1. Receiving a shipment of samples at the BPHL in Jacksonville

In reality, dry ice is a Class 9 miscellaneous dangerous good. As the dry ice sublimates, the volume of the carbon dioxide gas is significantly greater than the volume of solid dry ice, thus increasing the internal pressure of a sealed container. This buildup of pressure can result in a violent explosion. Even with properly vented packages, there are inherent dangers. Carbon dioxide gas displaces the oxygen in confined spaces such as an enclosed vehicle or aircraft. Anyone packaging dry ice must be a certified shipper.

On any given day, the Florida Department of Health (FDOH) Bureau of Public Health Laboratories (BPHL) receives between 800-1500 specimens for processing from around the State. Dangerous goods packages must be clearly labeled to provide information about the contents, the nature of the hazard and any special handling requirements. All markings and labels on dangerous goods packages must be clearly visible at all times.

An example of improper markings and labels that could have resulted in multiple exposures was a box received by the BPHL. The box, from all outward appearances, contained black toner for a copier. It was stored next to the copy machine until it was time for the toner replacement. When the box was opened-surprise!

Photograph 2. No markings or labels to indicate contents is anything but toner

(Continued on page 3)

PACKAGING 6.2 INFECTIOUS SUBSTANCES AND OTHER DANGEROUS GOODS (CONTINUED)

(Continued from page 2)

Instead of toner, it contained several-suspected *Mycobacterium tuberculosis* sputum specimens. Packages indicating this type of risk are opened in a Biosafety Level-3 (BSL-3) laboratory.

In this case, though not labeled as such, the toner box was used as an over pack. No required markings or labels were applied to notify the receiving staff at the laboratory of possible health risks. The inside packaging for this suspected Category B specimen was appropriate for the specimens it contained and staff immediately moved the package into the BSL-3 isolation laboratory. This real life experience emphasizes why it is important that only properly trained and certified personnel package specimens for transport and only properly trained and certified personnel transport those packages.

Photograph 3. This specimen was delivered to the laboratory security desk by a hospital courier as shown in the picture-no cushioning, no absorbent material or rigid outer container. Patient information is clearly visible to everyone.

Photograph 4. This package has an improper sized label. Placing an improper size label on a package carries a civil penalty of $1,000.00 per incident in accordance with 49CFR172.407(c).

Some issues seen quite frequently by the receiving departments at the BPHL include infectious substances delivered in a clear plastic bag with protected patient information clearly visible. This is a violation of HIPAA laws (photograph 3). Packages sent with the wrong size hazard label attached (photograph 4), packages with the improper use of over packs (photographs 5 and 6), and packages sent without appropriate outer packaging (photograph 7) are examples of non-compliance that could result in civil penalties assessed to the shipper.

Photograph 5. This package appears to contain hypodermic needles. No indications that this is an over pack containing several suspected Category B

(Continued on page 4)

PACKAGING 6.2 INFECTIOUS SUBSTANCES AND OTHER DANGEROUS GOODS (CONTINUED)

(Continued from page 3)

Photograph 6. Examples of improper use of over packs. In accordance with the 49CFR173.25(a)(4), failure to mark an over pack as required carries a civil penalty of $3,700.00 per incident.

Photograph 7. This package was sent through the US mail in an specimen mailer. In accordance with 49CFR 172.400, failure to label a package or applying a label that represents a hazard other than the hazard presented by the hazardous material in the package carries a civil penalty of $7,000.00 per incident.

Using the proper outer container is just a small part of mitigating associated risks. Category A and Category B infectious substances require the use of triple packaging. This means the primary receptacle is leak-proof and has enough cushioning materials to separate multiple fragile primary receptacles to keep them from breaking. There should also be sufficient appropriate absorbent material to absorb the entire contents of the primary receptacles should they break.

Photograph 8. Insufficient cushioning resulting in broken primaries.

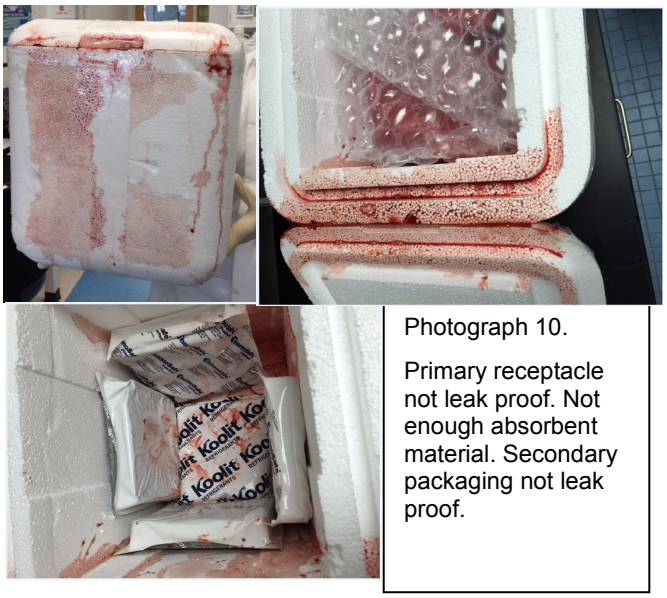
(Continued on page 5)

(Continued from page 4)

Photograph 9. Absorbency test using paper towels.

Also, not all paper towels or cotton balls are equal. Ensure there is enough absorbent material to absorb all liquids, including any melted ice or sweat from gel packs. If you are unsure of the absorbency of your selected material, then you should test it to determine the amount needed to absorb all of the liquid you plan to ship.

The secondary packaging should also be leak proof in case the primary packaging fails. The secondary packaging must be securely placed inside the outer packaging with suitable cushioning to hold it in place. Do not overfill it with primary receptacles to the point the cushioning materials and absorbent materials will no longer function as intended. Remember, the itemized list of contents is not a suitable cushioning material around the primary receptacle. It should go between the secondary and outer packaging.



Photograph 10.

Primary receptacle not leak proof. Not enough absorbent material. Secondary packaging not leak proof.

Photograph 11. Outer package must be rigid and of adequate strength for its contents

For both Category A and Category B infectious substances, the outer packaging must be rigid and of adequate strength for its capacity, weight and intended use. At least one surface of the outer packaging must be a minimum of 100mm x 100mm (4 x 4 inches) to accommodate the hazard labels and markings.

(Continued on page 6)

(Continued from page 5)

Who should be trained to package and ship? In accordance with the Code of Federal Regulations Title 49, 172.704 (49CFR 172.704), anyone who handles, offers to transport, or transports infectious substances and other dangerous goods, such as dry ice, or who performs or is responsible for performing a pre-transportation function should be trained. Pre-transportation functions include, but are not limited to, the following:

(1) Determining the hazard class of a hazardous material.
(2) Selecting a hazardous materials packaging.
(3) Filling a hazardous materials packaging, including a bulk packaging.
(4) Securing a closure on a filled or partially filled hazardous materials package or container or on a package or container containing a residue of a hazardous material.
(5) Marking a package to indicate that it contains a hazardous material.
(6) Labeling a package to indicate that it contains a hazardous material.
(7) Preparing a shipping paper.
(8) Providing and maintaining emergency response information.
(9)Reviewing a shipping paper to verify compliance with the hazardous materials regulations (HMR) or international equivalents.[1]

There are four specific subjects the training must cover to comply with the 49CFR 172.704). The subjects are general awareness/familiarization, function specific, safety, and security awareness. The training is recurrent. The Department of Transportation (DOT) states, "A hazmat employee must receive the training required by this subpart at least once every three years"[1]. However, to comply with the International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA), it must occur every two years to ensure the employee's knowledge is up-to-date with the current regulations.

The employer must create and retain a record of training for each employee involved in the preparing, packaging, or transport of dangerous goods. The record of training must be retained for three years from the most current training for as long as that employee is employed and for 90 days thereafter. The employee's record of current training must be made available upon request to an authorized official of the Department of Transportation or of an entity explicitly granted authority to enforce the hazardous materials regulations. The record must include:

(1) The hazmat employee's name;

(Continued on page 7)

(Continued from page 6)

(2) The most recent training completion date of the hazmat training;
(3) A description, copy, or the location of the training materials used to meet the requirements in the 49CFR 172.704;
(4) The name and address of the person providing the training; and
(5) Certification that the hazmat employee was trained and tested.[1]

Why is training important? In the United States (U.S.), the Department of Transportation (DOT) regulates the transport of dangerous goods. They recently updated their fines for violations of the hazardous materials regulations. 49CFR107 Appendix A to Subpart D of Part 107—Guidelines for Civil Penalties lists frequently cited violations and general guidelines used in making penalty determinations in enforcement cases.[4] If an individual or institution is found to be noncompliant with the regulatory requirements, they are subject to a civil penalty, with a maximum penalty of $75,000 for each violation. The maximum increases to $175,000 if the violation results in death, substantial property damage, serious illness or severe injury to any person (49CFR 107.329). The minimum civil penalty for training violations is $450.[1, 2]

In situations where a person willfully or recklessly violates the hazardous material regulations, that person may be subject to criminal investigation, with the potential of up to five years imprisonment. The maximum imprisonment time is ten years when the violation causes an accident resulting in death or bodily injury to any person (49 CFR 107.333).[1, 2]

When it comes to shipping hazardous materials, the U.S. Department of Transportation is imposing higher penalties for non-compliance. The consequences of not performing due diligence, which starts with properly training hazmat employees, exposes facilities and individuals to serious fines. (See Table 1) The solution is simple. All personnel involved in shipping hazardous materials should receive proper training either in-house or by an experienced and reputable organization.

The FDOH BPHL is sponsoring, through the CDC Cooperative Agreement Grant for Public Health Emergency Preparedness, "2016 Division 6.2 Infectious Substances Packaging and Shipping Training". This training is primarily for our sentinel laboratory partners, but is also available to other hospital and County Health Department laboratory personnel. Non-Sentinel laboratory personnel are welcome to attend if space is available. The BPHL offers these classes at no charge to the participants, but the classes are limited and preregistration is required.

(Continued on page 8)

PACKAGING 6.2 INFECTIOUS SUBSTANCES AND OTHER DANGEROUS GOODS (CONTINUED)

(Continued from page 7)

These classes are designed to inform and communicate the requirements for safe shipping to anyone involved in the transport operation. Saf-T-Pak Incorporated will conduct twenty classes throughout Florida between March 21, 2016 and June 7, 2016. (See the training schedule on page 8 and 9) Participants will learn the responsibilities of the shipper, carrier, and receiver in accordance with the CFR 49: Transportation Parts 100-185 (49CFR 100-185), ICAO and IATA Dangerous Goods Regulations (DGR). A hands-on exercise will emphasize how to properly package and ship Category A and Category B infectious substances and other dangerous goods, such as dry ice by air and ground.

It is not required to attend the training provided by the BPHL. The employer or one of many other public or private sources including online training may provide this training. However, the employer is responsible for ensuring that each employee who performs any function in the packaging or shipping of a hazardous material receives training in the specific areas and testing by an appropriate means prior to performing that function. Certification only applies to the areas in which they can successfully perform their duties.

To register, please log in to your FL TRAIN account at https://fl.train.org/Desktopshell.aspx. If you do not currently have a FL TRAIN account, click on "Create Account" and complete the registration. Once registered as a TRAIN user, the course can be found by typing in the search box either "FDOH 2016 Division 6.2 Infectious Substances Packaging and Shipping" or the course identification number 1062483. Click on the registration tab. You must select credit type and choose either CEU/CE or None. You must type your license number in the box or if you do not have a license, type "none". Then select the session you wish to attend by clicking on "Get Approval".

For additional information on how to register for one of the classes, please contact **Betty Wheeler at Betty.Wheeler@flhealth.gov or (904) 791-1568** at BPHL Jacksonville or **Leah Kloss at Leah.Kloss@flhealth.gov or (813) 974-4009** at BPHL-Tampa.

References.

1. Electronic Code of Federal Regulations Title 49: Transportation Parts 100 - 185. Retrieved on February 9, 2015 from http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title49/49cfrv2_02.tpl
2. Saf-T-Pak, Inc. 2015 Compliance Training Reference Manual for the Safe Transport of Division 6.2 Infectious Substances, Biological Specimens, Dry Ice & Related Materials.
3. Hazardous Materials Regulations of the Department of Transportation (49CFR-Parts 105-107, 109, 110,130, 171-180, 209, 397 and 1580) Part 107, Subpart D – Enforcement January 29, 2015.
4. Electronic Code of Federal Regulations Title 49: Transportation Parts 100 - 185. Appendix A to Subpart D of Part 107—Guidelines for Civil Penalties http://www.ecfr.gov/cgi-bin/text-idx?

2016 INFECTIOUS SUBSTANCES PACKAGING AND SHIPPING TRAINING SCHEDULE

1. Monday, March 21, 2016	**Florida Department of Health-Bay– 597 W 11th St, Panama City, FL 32401Auditorium**
2. Tuesday, March 22, 2016	**Florida Department of Health-Escambia - 1295 W. Fairfield Dr, Pensacola, FL 32501 Room #302/303**
3. Wednesday, March 23, 2016	**Florida Department of Health-Okaloosa – 810 E. James Lee Blvd. Crestview, FL 32539 Room #73 A&B**
4. Friday, April 1, 2016	**Florida Department of Health-Volusia - 1845 Holsonback Drive, Daytona Beach, FL 32117 Main Conference Room 516A**
5. Tuesday, April 12, 2016	**Department of Agriculture and Consumer Affairs – Conner Administration Building, 3125 Conner Boulevard, Tallahassee, FL 32399 Eyster Auditorium**
6. Tuesday, April 19, 2016	**Florida Department of Health-Marion - 1801 SE 32nd Ave, Ocala, FL 34471 Auditorium # 1&2**
7. Thursday, April 21, 2016	**Florida Department of Health Bureau of Public Health Laboratories-Jacksonville, 1217 Pearl Street, Jacksonville, FL 32202 2nd Floor Porter Auditorium**
8. Wednesday, May 4, 2016	**Florida Department of Health-Lee - 83 Pondella Dr, N Ft Myers, FL33916**
9. Thursday May 5, 2016	**Highlands County EOC - 6850 W. George Blvd. Sebring, FL 33875**
10. Friday, May 6, 2016	**Florida Department of Health Bureau of Public Health Laboratories-Tampa, 3602 Spectrum Blvd, Tampa FL 33612 Conference Center**

2016 INFECTIOUS SUBSTANCES PACKAGING AND SHIPPING TRAINING SCHEDULE

11. Monday, May 9, 2016	**Florida Department of Health Bureau of Public Health Laboratories-Tampa, 3602 Spectrum Blvd, Tampa FL 33612 Conference Center**
12. Wednesday, May 11, 2016	**Florida Department of Health-Miami- Down town - 1350 NW 14 Street, Miami FL 33125 Large Conference room**
13. Thursday, May 12, 2016	**Florida Department of Health-Miami-Doral - 8600 NW 17th St, Miami, FL 33126 2nd Floor Conference room**
14. Monday, May 16, 2016	**Florida Department of Health-Broward – 780 SW 24th St. FT Lauderdale FL 33315 Administrative Auditorium-2nd floor**
15. Tuesday, May 17, 2016	**Florida Department of Health-Broward – 780 SW 24th St. FT Lauderdale FL 33315 Administrative Auditorium-2nd floor**
16. Monday, May 23, 2016	**Florida Department of Health-Palm Beach - 800 Clematis St, West Palm Beach, FL 33401**
17. Tuesday May 24, 2016	**Florida Department of Health-Palm Beach - 800 Clematis St, West Palm Beach, FL 33401**
18. Thursday, June 2, 2016	**Florida Department of Health-Orange - 6101 Lake Ellenor Dr, Orlando, FL 32809 Auditorium**
19. Friday, June 3, 2016	**Florida Department of Health-Orange - 6101 Lake Ellenor Dr, Orlando, FL 32809 Auditorium**
20. Tuesday, June 7, 2016	**Florida Department of Health Bureau of Public Health Laboratories-Jacksonville, 1217 Pearl Street, Jacksonville, FL 32202 2nd Floor Porter Auditorium**

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Editor - Betty Wheeler

CHEMICAL THREAT (CT) PREPAREDNESS TRAINING

The CT laboratory coordinators continue to reach out to the health and medical community by offering training for CT preparedness at hospitals and county health departments (CHDs). This training consists of two courses: Chemical Terrorism Awareness and Collecting Clinical Specimens After a Chemical Terrorism Event. Hospital and CHD staff play an important role in the response to a chemical exposure event since clinical specimens will be collected for analysis. For your convenience and to increase participation, this training can be presented at your facility. Each course lasts approximately one hour with one 15-minute break between courses. Florida clinical laboratory and nursing continuing education credits will be offered. Training manuals, "hands on" exercise materials, and CT preparedness kits will be provided. This training is recommended for physicians, nurses, epidemiologists, emergency department personnel, phlebotomists, hospital and health department laboratory personnel, and others who may collect clinical specimens. Contact the CT laboratory coordinators in your region for more information (see the Bureau of Public Health Laboratories Directory on the back of this document for contact information).

LABORATORY RESPONSE NETWORK (LRN) TRAINING—BIOLOGICAL DEFENSE

The Bureau of Public Health Laboratories is currently offering an LRN sentinel laboratory training course at no cost to you at your facility. This training follows the American Society for Microbiology (ASM) Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases. Scheduling the training at your facility is a relatively easy process. Determine when you would like to have the training and how many people will be attending. A time will be set up that is convenient for all. The training materials are provided, as well as the biodefense reference manuals for your laboratory.

"at no cost to you at your facility"

The training syllabus includes: 1) an overview of the LRN; 2) the ASM protocols for ruling out potential bioterrorism agents and how to refer a sample to the state LRN Public Health Reference Laboratory when a bioterrorism agent cannot be ruled out; 3) the role of the sentinel laboratory in responding to pandemic influenza; 4) a brief introduction to packaging and shipping of infectious substances; 5) an introduction to the CDC Select Agent Program; and 6) the College of American Pathologists Laboratory Preparedness Exercise (CAP LPX).

This class awards Florida clinical laboratory continuing education credits based on five hours of instruction. Please contact Betty Wheeler at (904) 791-1568 (Betty.Wheeler@FLhealth.gov) to schedule a class for your facility.

Florida Department of Health
Bureau of Public Health Laboratories—Directory
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